

AMENDMENTS TO THE CLAIMS

Listing of Claims:

This listing of claims will replace all previous listings.

Claim 1. (Original) A method of conducting a clinical trial of a device or method or substance of treatment on a plurality of trial participants, the method including the steps of :

establishing an electronic database in communication with one or more remote computers;

entering predetermined trial parameters of the conduct of the clinical trial into the database;

programming the database and remote computers to provide a predetermined interface for accepting predetermined information relating to the trial being entered by trial participants, administrators and/or auditors;

recording particulars of the trial participants and forming ordered registration information on the database;

forming randomised particulars of the trial participants in the database from the ordered registration information, the randomised particulars including the allocation of an identifier label;

assigning the device or method or substance of treatment to the randomised particulars of each trial participant;

entering trial data via the predetermined interface into the database by an authorized trial participant;

producing a report of data entered onto the database in response to predetermined reporting conditions;

controlling and tracking the ordering, allocation and dispensing of the device or method or substance of treatment and compiling a method or substance inventory record on the database; and

terminating the clinical trial in response to predetermined termination conditions.

Claim 2. (Original) A method according to claim 1 wherein the method is for conducting a clinical trial of a pharmaceutical substance.

Claim 3. (Currently Amended) A method according to claim 1 ~~or 2~~ wherein the database and remote computers communicate via internet communications.

Claim 4. (Currently Amended) A method according to claim 2 ~~or 3~~ wherein the predetermined trial parameters include the dosage rates of the pharmaceutical substance to be given to the selected trial participants.

Claim 5. (Currently Amended) A method according to ~~any one of the preceding claims~~ Claim 1 wherein the trial data is entered onto the remote computer or the database and wherein only specific volumes and forms of the data are acceptable by the remote

computer or central database.

Claim 6. (Currently Amended) A method according to ~~any one of claims 1 to 5~~ Claim 1 wherein the trial administrators have access to view any entered data or add any predetermined data to the information in the database, and the trial auditors have access to view any entered information in the database.

Claim 7. (Currently Amended) A method according to ~~any one of claims 1 to 6~~ Claim 1 wherein the recorded particulars of the selected participants in the ordered registration information are restricted to predetermined trial administrators and auditors.

Claim 8. (Currently Amended) A method according to ~~any one of claims 1 to 7~~ Claim 1 wherein the randomised particulars of the selected trial participants and trial information relating to those participants are available to all trial participants.

Claim 9. (Currently Amended) A method according to ~~any one of claims 1 to 8~~ Claim 1 including the step of generating reminders from the database at predetermined times after trial data is entered, the reminders being displayed to predetermined trial participants upon access to the remote computers or the database.

Claim 10. (Currently Amended) A method according to ~~any one of claims 1 to 9~~ Claim 1 wherein the trial report of entered data reports on all data entered into the database at a

predetermined time or in response to the entry of specific data types or quantities.

Claim 11. (Currently Amended) A method according to ~~any one of claims 2 to 10~~ Claim 2 wherein the step of controlling and tracking the movement of the pharmaceutical substances and recording the pharmaceutical substance inventory record on the database further includes the step of selectively establishing communication with the pharmaceutical substance supplier and placing an electronic order.

Claim 12. (Currently Amended) A method according to ~~any one of the preceding claims~~ Claim 1 including the steps of:

providing one or more local trial administration centres for conducting the clinical trial;

assigning one or more trial participants to each local trial administration centre;

determining a payment to each local trial administration centre for conducting the clinical trial; and

effecting the determined payment to each local trial administration centre at predetermined times from the commencement of the clinical trial.

Claim 13. (Original) A method according to claim 12 wherein the determined payments are determined in response to types of treatment delivered to trial participants and a standard amount per patient per clinical trial visit.

Claim 14. (Currently Amended) A method according to claim 12 ~~or 13~~ including the step of providing financial reports relating to the determined payments including payments earned by the local trial administration centres, payments made thereto, payments outstanding to each local trial administration centre, and over-payments previously made to any local trial administration centre.

Claim 15. (Currently Amended) A method according to ~~any one of claims 2 to 14~~ Claim 2 wherein the trial termination conditions include a lapsing of a predetermined time, consumption of a predetermined amount of pharmaceutical substance by one or more trial participants, or the occurrence of an adverse event of a trial participant.

Claim 16. (Currently Amended) A method according to ~~any one of the preceding claims~~ Claim 1 including a plurality of remote computers each being disposed at individual sites remote from the database and being configured to accepted on predetermined data.

Claim 17. (Currently Amended) A method according to ~~any one of claims 2 to 16~~ Claim 2 wherein a plurality of pharmaceutical substances are simultaneously trialed and controlled by the database.

Claim 18. (Currently Amended) A method according to ~~any one of the preceding claims~~ Claim 1 wherein the remote computers are selected from the group consisting of : personal digital assistants, laptop computers, desktop computers, tablet personal

computers, mobile telephones, pagers and dedicated computing devices.

Claim 19. (Currently Amended) A method according to ~~any one of the preceding claims~~ Claim 1 wherein the remote computers and electronic database communicate by wireless, electrical cable and/or optical fibre networks.

Claim 20. (Currently Amended) A method according to ~~any one of the preceding claims~~ Claim 1 wherein the electronic database includes a computer server in combination with a data storage device.

Claim 21. (Original) A system for conducting a clinical trial of a device or method or substance of treatment on a plurality of trial participants, the system including:

- a database having a memory means in communication with a database means;
- one or more trial sites each having a remote computer located remotely from the database and in communication therewith;
- the database being configured to receive predetermined parameters of the trial;
- both the database and the remote computers being configured to receive predetermined trial data from one or more trial participants; and
- the database being configured to control and track the ordering, allocation and dispensing of the device or method or substance of treatment and compiling a device or method or substance inventory record on the central database;

wherein the database being configured to terminate the clinical trial in response to one or more predetermined trial termination conditions.

Claim 22. (Original) A system according to claim 21 configured for conducting a clinical trial of a pharmaceutical substance.

Claim 23. (Original) A system according to claim 22 wherein the database is configured to receive and record information relating to the trial participants and also to form randomised particulars of the trial participants in the database including the determination of which trial participants receive the pharmaceutical substance and which receive a placebo.

Claim 24. (Currently Amended) A system according to ~~any one of claims 21 to 23~~ Claim 21 wherein the database is configured to produce a report of data entered into the database relating to the trial.

Claim 25. (Currently Amended) A system according to ~~any one of claims 21 to 24~~ Claim 21 wherein the database is configured to generate reminders to the trial administrators at a predetermined time after trial data is entered or the trial commenced, the reminders being displayed upon the trial administrators accessing a remote computer.

Claim 26. (Currently Amended) A system according to ~~any one of claims 21 to 25~~ Claim 21 wherein the remote computers are selected from the group consisting of: personal digital assistants, laptop computers, desktop computers, tablet personal computers, mobile telephones, pagers and dedicated computing devices.

Claim 27. (Currently Amended) A system according to ~~any one of claims 21 to 26~~ Claim 21 wherein the remote computers and database communicate by wireless, electrical cable and/or optical fibre networks.

Claim 28. (Currently Amended) A system according to ~~any one of claims 21 to 27~~ Claim 21 wherein the database includes a computer server in combination with a data storage device.

Claim 29. (Currently Amended) A system according to ~~any one of claims 21 to 28~~ Claim 21 being configured to:

provide one or more local trial administration centres for conducting the clinical trial;

assign one or more trial participants to each local trial administration centre;

determine a payment to each local trial administration centre for conducting the clinical trial; and

effect the determined payment to each local trial administration centre at predetermined times from the commencement of the clinical trial.

Claim 30. (Original) A system according to claim 29 wherein the determined payments are determined in response to types of treatment delivered to trial participants and a standard amount per patient per clinical trial visit.

Claim 31. (Currently Amended) A system according to claim 29 ~~or 30~~ configured to provide financial reports relating to the determined payments including payments earned by the local trial administration centres, payments made thereto, payments outstanding to each local trial administration centre, and over-payments previously made to any local trial administration centre.